REMARKS

Claims 1-60 are pending in the application. Claims 1-3, 6, 7, 16, 20, 21, 27-48, and 50-60 are currently amended. Claim 49 is currently canceled.

I. Claim Rejections Under 35 U.S.C. 101

Claims 1-26 and 31 are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions. In particular, the Examiner asserts that the claims do not qualify as a statutory process since they are not tied to another statutory class, can be performed without the use of a particular apparatus, and do not recite steps transforming underlying subject matter to a different state or thing. Applicant respectfully traverses.

Under current law, the machine-or-transformation test is the applicable test for patent-eligible subject matter. In re Bilski, 545 F.3d 943, 960 (Fed. Cir 2008). The machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. Id. at 961. Accordingly, Applicant has amended Claims 1-3, 6, 7, 16 and 20 to clarify that the claimed process is executed on a particular machine comprising, *inter alia*, depending on the claim, one or more computing devices, a display device operatively connected to at least one of the one or more computing devices, and/or a memory operatively connected to at least one of the one or more computing devices. The claims, as amended, are now directed to statutory subject matter.

Claims 4, 5, 8-15, 17-19 each depend, directly or indirectly, on Claim 1, and are thus now directed to statutory subject matter. Claims 21-26 depend, directly or indirectly, on Claim 20, and are thus now directed to statutory subject matter. Claim 31 is addressed below.

Claims 27-30, and 32-60 stand rejected under 35 U.S.C. 101 as directed to non-statutory subject matter. Applicant respectfully traverses.

In re Beauregard, 53 F.3d 1583 (Fed. Cir. 1995) firmly established the principle that computer programs embodied in a tangible medium, such as floppy diskettes or other form of computer readable medium, are patentable subject matter under 35 U.S.C. § 101 (they are

properly classed as a manufacture.) The principles of In re Beauregard retain their vitality even in the wake of In re Bilski. See, e.g. Ex parte Li, Appeal 2008-1213, page 6, BPAI , November 6, 2008. See also MPEP § 2106.01, I. Accordingly, Applicant has amended Claims 31, 27-30, and 32-48, and 50-60 to claim a computer-readable medium having computer-executable instructions, and are thus now, as amended, directed to statutory subject. Claim 49 has been canceled without prejudice.

Claims 27 and 54 stand rejected under 35 U.S.C. 101 as being directed to systems that comprise a computer executable program or software, which, Examiner asserts, is not a patentable statutory class. Applicant has amended Claims 27 and 54 to claim a computer-readable medium having computer-executable instructions, and are thus now, as amended, directed to statutory subject.

Therefore, for all of the above reasons, Applicant respectfully requests that the rejection of Claims 1-60 under 35 U.S.C. 101 be withdrawn.

II. Claim Rejections Under 35 U.S.C. 112, Second Paragraph

Claims 6-13, and 27-60 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses.

In particular, the Examiner asserts that in Claim 6 and its dependant claims, Claims 7-13, the term "drug state data" in the process step "storing in a memory a drug state data for at least one subject's drug usage" is unclear. Applicant hereby amends Claim 7 to more clearly state that the process step provides for "storing in a memory, drug state data comprising at least one subject's drug usage." Applicant also notes that the meaning of the term drug state data is discussed in, *inter alia*, paragraphs [0012], [0026] and [0055].

With respect to Claim 7, the claim states that memory used to store drug data is "remotely located." The Examiner asserts that the claim is indefinite, as it is unclear what the memory is remotely located from, and claims 1 and 6 from which claim 7 depends, are method claims. Claim 34, containing the same language as claim 7, is rejected under the same analysis. The Applicant hereby amends the claims to clarify that the memory is remote or external from,

in Claim 7, the computing device which is running at least some steps of the method, and in Claim 34, the computer-readable medium having computer-executable instructions for the method.

With respect to Claims 27 and 54, the Examiner observes that the claims are directed to systems, yet recite method steps. The Examiner argues it is unclear if Applicant is claiming a system or a method. Claims 28-30, 32-45 and claims 55-60, as dependents of claims 27 and 54, stand rejected under the same analysis. With respect to Claim 31, the Examiner asserts that the claim is indefinite because it recites a system, but depends from claim 26 which is a method claim. Claims 27-30, 32-45 and claims 54-60 have all been amended to clarify that that the claims are directed to a computer-readable medium having computer-executable instructions for a method.

Therefore, for all of the above reasons, Applicant respectfully requests that the rejection of Claims 6-13, and 27-60 under 35 U.S.C. 112, second paragraph, be withdrawn.

III. Claim Rejections Under 35 U.S.C. 103(a)

Claims 1-8, 18, 19, 27-35, 46, 49, 50, 52 and 53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. Pub. No. 2002/0026330 to Klein ("Klein".) Applicant respectfully traverses.

Independent Claim 1, as amended, is a method of visually presenting future drug use resulting from altered usage in a subject. At least one drug associated with a predetermined digital patient information is selected. A first start time for administering at least one drug dosage is identified. An initial future drug usage period from the digital patient information and the first start time is determined. At least one subsequent start time for administering at least one subsequent drug dosage, said subsequent start time being a function of an alteration in the subject's future drug usage is identified. A subsequent future drug usage period from the digital patient information and the at least one subsequent start time is determined. At least the determining an initial future drug usage step and the determining a subsequent future drug usage period step are performed on one or more computing devices.

Independent Claim 27 is a computer-readable medium having computer-executable instructions for a method for visually presenting future drug use resulting from altered usage in a subject. The method comprises the following steps. Data identifying at least one drug associated with the digital patient information stored on a program memory is accepted via an input. A first start time for at least one drug dosage is accepted, via an input. An initial future drug usage period from the digital patient information and the first start time is determined. Data identifying at least one subsequent start time for at least one subsequent drug dosage; said subsequent start time being a function of altered drug use in a subject is accepted, via the input. A subsequent future drug usage period is determined from the digital patient information and the at least one subsequent start time.

Klein is directed to a system and method to manage the administration of medication to a patient. The system maintains a database of medications to be taken by a patient. The database includes at least the medication name, dosage, and administration time or frequency of administration. In addition, the database may contain specific cautionary warnings and notices regarding the administration of the medication. The system uses the medication schedule to determine the time that a particular medication should be administered. Once an administration time has been determined, a notification is provided to a patient or caregiver at the appropriate time indicating the particular medication to administer. The system then determines the identity of a medication chosen by the patient or caregiver to be administered, and compares this medication to the medication identified in the medication schedule and determines whether the correct medication has been chosen by the patient or caregiver for administration, and reports the results.

With respect to Claim 1, Klein does not disclose a method wherein a first start time for administering at least one drug dosage is identified and an initial future drug usage period is determined from the digital patient information and the first start time, at least one subsequent start time for administering at least one subsequent drug dosage is identified, the subsequent start time being a function of an alteration in the subject's future drug usage, and determining a subsequent future drug usage period from the digital patient information and the at least one subsequent start time. Rather, Klein discloses a system that only determines the next date a medication should be taken based on actual prior administration. See Klein, paragraph [0032].

Furthermore, Klein does not disclose a system wherein a subsequent start date is determined by an alteration in a drug's future usage. At most, Klein discloses a system that can support complex dosage schedules where administration levels, routines and instructions may change each specific time the drug is administered. See Klein, paragraph [0010]. Therefore Claim 1 contains at least one element not disclosed or suggested by Klein. Claims 2-8, 18 and 19 each depend, directly or indirectly, from Claim 1, and thus also contain at least one element not disclosed or suggested by Klein.

With respect to Claim 27, Klein does not disclose accepting a first start time for at least one drug dosage via an input, determining an initial future drug usage period from the digital patient information and the first start time, accepting data identifying at least one subsequent start time for at least one subsequent drug dosage; said subsequent start time being a function of altered drug use in a subject via the input, and determining a subsequent future drug usage period from the digital patient information and the at least one subsequent start time. Rather, Klein discloses a system that only determines the next date a medication should be taken based on actual prior administration. See Klein, paragraph [0032]. Furthermore, Klein does not disclose a system wherein a subsequent start date is determined by an alteration in a drug's future usage. At most, Klein discloses a system that can support complex dosage schedules where administration levels, routines and instructions may change each specific time the drug is administered. See Klein, paragraph [0010]. Therefore Claim 27 contains at least one element not disclosed or suggested by Klein. Claims 26-35, 46, 49, 50, 52 and 53 each depend, directly or indirectly, from Claim 27, and thus also contain at least one element not disclosed or suggested by Klein.

It is well established that, in order to show obviousness, all limitations must be taught by the prior art. In Re Royka, 180 U.S.P.Q. 580, 490 F.2d 981 (CCPA 1974); MPEP § 2143.03. It is error to ignore specific limitations distinguishing over the references. In Re Boe, 184 U.S.P.Q. 38, 505 F.2d 1297 (CCPA 1974); In Re Saether, 181 U.S.P.Q. 36, 492 F.2d 849 (CCPA 1974); In Re Glass, 176 U.S.P.Q. 489, 472 F.2d 1388 (CCPA 1973). As argued above, Claims 1-8, 18, 19, 27-35, 46, 49, 50, 52 and 53 contain limitations not taught or suggested by Klein and are therefore patentable over Klein.

Therefore, for all of the above reasons, Applicant respectfully requests that the rejection of Claims 1-8, 18, 19, 27-35, 46, 49, 50, 52 and 53 under 35 U.S.C. 103(a) as being unpatentable over Klein be withdrawn.

Claims 9-17, 36-45, 47, 48 and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Klein in view of U.S. Pat. Pub. No. 2003/0074234 to Stasny ("Stasny".) Applicant respectfully traverses.

Stasny discloses a customer-centered pharmaceutical product and information distribution system. The system includes a customer terminal and a pharmacy terminal, both terminals coupled to a network. The pharmacy terminal is coupled to a pharmacy management system that has a database. A third terminal is also connected to the network. The third terminal is selected from the group consisting of an insurance provider terminal, a fiscally responsible party terminal, a physician terminal, a government agency terminal, a drug manufacturer terminal, and a flexible benefits operator terminal. A server is also coupled to the network. The server has a site accessible by the customer, the pharmacy, and the third terminal. The server also has a database that is synchronized with the database of the pharmacy management system.

Claims 9-17 each depend, directly or indirectly, on Claim 1. Stasny does nothing to remedy the deficiencies of Klein cited above with reference to Claim 1. In particular, neither Klein nor Stasny discloses or suggest a method wherein a first start time for administering at least one drug dosage is identified and an initial future drug usage period is determined from the digital patient information and the first start time, at least one subsequent start time for administering at least one subsequent drug dosage is identified, the subsequent start time being a function of an alteration in the subject's future drug usage, and determining a subsequent future drug usage period from the digital patient information and the at least one subsequent start time. Therefore Claims 9-17 contain at least one element not disclosed or suggested by the asserted combination of Klein and Stasny.

Claims 36-45, 47, 48 and 51 each depend on Claim 27. Stasny does nothing to remedy the deficiencies of Klein cited above with reference to Claim 27. In particular, neither Klein nor Stasny disclose or suggest accepting a first start time for at least one drug dosage via an input, determining an initial future drug usage period from the digital patient information and the first

start time, accepting data identifying at least one subsequent start time for at least one subsequent drug dosage; said subsequent start time being a function of altered drug use in a subject via the input, and determining a subsequent future drug usage period from the digital patient information and the at least one subsequent start time. Therefore Claims 36-45, 47, 48 and 51 contain at least one element not disclosed or suggested by the asserted combination of Klein and Stasny.

Therefore, for all of the above reasons, Applicant respectfully requests that the rejection of Claims 9-17, 36-45, 47, 48 and 51 under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Stasny be withdrawn.

Claims 20-22, and 54-56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330 in view of U.S. Patent No. 6,769,602 to Rottem. Applicant respectfully traverses.

Rottem discloses a feto-maternal calendar calculator that provides for calculating the gestational age of a fetus from the calendar date of the mother's last menstrual cycle. Using the calculated gestational age, the user of the calendar calculator may determine appropriate growth of fetal organs, determine the earliest time for detection of fetal anomalies, establish periods of risk to the fetus from drugs used by the mother, determine the appropriate times for testing for fetal anomalies, genetic abnormalities, or other fetal biochemical milestones. The calendar calculator of the present invention is designed for ease of use and for providing information previously unavailable to obstetricians and diagnostic technicians.

Independent Claim 20 is a method of visually presenting future drug use resulting from altered usage in a subject. At least one drug associated with a predetermined digital patient information is selected. At least one start time for administering a dosage of the at least one drug is identified. A future drug usage period from the digital patient information and the at least one start time is determined. A risk period is determined from the digital patient information and the at least one start time, said risk period being associated with the at least one future drug usage period.

Neither Klein nor Rottem disclose or suggest a method where at least one start time for administering a dosage of the at least one drug is identified and a future drug usage period is

determined from the digital patient information and at least one start time. At most, Klein discloses a system that only determines the next date a medication should be taken based on actual prior administration. See Klein, paragraph [0032]. Rottem does not disclose or suggest any methods directed to determining periods of drug use.

Neither Klein nor Rottem disclose a risk period which is determined from the digital patient information and at least one start time, the risk period being associated with at least one future drug usage period. In the present Office Action, Examiner admits that Klein makes no mention of determining a risk period of any kind. Rottem mentions, with no further elaboration, establishing periods of risk to the fetus from drugs used by the mother. See Rottem, Abstract. Rottem does not, however, explicitly disclose associating the periods of risk period with a future drug use period determined from digital patient information and at least one start time.

Therefore Claim 20 contains at least one element not disclosed or suggested by the suggested combination of Klein and Rottem. Claims 21 and 22 each depend, directly or indirectly, from Claim 20, and thus also contain at least one element not disclosed or suggested by the suggested combination of Klein and Rottem.

Independent Claim 54 is a computer-readable medium having computer-executable instructions for a method for visually presenting future drug use resulting from altered usage in a subject. The method comprises the following steps. Data identifying at least one drug associated with digital patient information stored on a program memory. At least one start time for at least one drug dosage is accepted, via the input. At least one future drug usage period is determined from the digital patient information and the at least one first start time. A risk period is determined from the digital patient information and at least one start time, said risk period being associated with the at least one future drug usage period.

Neither Klein nor Rottem disclose or suggest a method wherein at least one start time for at least one drug dosage is accepted, via the input, and at least one future drug usage period is determined from the digital patient information and the at least one first start time. At most, Klein discloses a system that only determines the next date a medication should be taken based on actual prior administration. See Klein, paragraph [0032]. Rottem does not disclose or suggest any methods directed to determining periods of drug use.

Neither Klein nor Rottem disclose a risk period which is determined from the digital patient information and at least one start time, the risk period being associated with at least one future drug usage period. In the present Office Action, Examiner admits that Klein makes no mention of determining a risk period of any kind. Rottem mentions, with no further elaboration, establishing periods of risk to the fetus from drugs used by the mother. See Rottem, Abstract. Rottem does not, however, explicitly disclose associating the periods of risk period with a future drug use period determined from digital patient information and at least one start time.

Therefore Claim 54 contains at least one element not disclosed or suggested by the suggested combination of Klein and Rottem. Claims 55 and 56 each depend, directly or indirectly, from Claim 54, and thus also contain at least one element not disclosed or suggested by the suggested combination of Klein and Rottem.

Therefore, for all of the above reasons, Applicant respectfully requests that the rejection of Claims 20-22, and 54-56 under 35 U.S.C. 103(a) as being unpatentable over Klein in view of Rottem be withdrawn.

VIII. Conclusion

Having responded to all objections and rejections set forth in the outstanding Office Action, it is submitted that claims 1-48, and 50-60 are in condition for allowance and Notice to that effect is respectfully solicited. In the event that the Examiner is of the opinion that a brief telephone or personal interview will facilitate allowance of one or more of the above claims, the Examiner is courteously requested to contact applicant's undersigned representative.

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 50-2638. If an extension of time is required, this should be considered a petition therefor.

Respectfully submitted,

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